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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,416	02/19/2002	Mechthild Rieping	218162US0X	2415
22850	7590	05/27/2008	EXAMINER	
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			STEADMAN, DAVID J	
			ART UNIT	PAPER NUMBER
			1656	
			NOTIFICATION DATE	DELIVERY MODE
			05/27/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/076,416	Applicant(s) RIEPING ET AL.	
	Examiner David J. Steadman	Art Unit 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,33,35-42 and 2528 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23,25-28,33 and 39-42 is/are rejected.
- 7) ☒ Claim(s) 35-38 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1] In view of the new rejection set forth below, the finality of the Office action filed on 11/30/07 is withdrawn.
- [2] Claims 23, 25-28, 33, and 35-42 are pending in the application.
- [3] Receipt of a terminal disclaimer, filed on 4/30/08, is acknowledged.
- [4] Applicant's arguments filed on 4/30/08 in response to the Advisory action filed on 4/23/08, are acknowledged. Applicant's arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- [6] Claim(s) 23, 25-28, 33, and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farwick et al. (US Patent 6,818,432; "Farwick-1"), Farwick et al. (US

Patent 7,205,131; "Farwick-2"), Farwick et al. (US Patent Application Publication 2003/0224499; "Farwick-3"), Farwick et al. (US Patent Application Publication 2004/0005675; "Farwick-4"), Farwick et al. (US Patent Application Publication 2005/0009143; "Farwick-5") Burke (US Patent Application Publication 2006/0014259; "Burke-1"), Burke (US Patent Application Publication 2003/0199045; "Burke-2"), Burke (US Patent Application Publication 2003/0109014; "Burke-3"), Burke et al. (US Patent Application Publication 2005/0112733; "Burke-4"), Burke et al. (US Patent Application Publication 2006/0014259; "Burke-5"), Hans et al. (US Patent Application Publication 2003/0175911; "Hans"), Nampoothiri et al. (US Patent Application Publication 2002/0042107; "Nampoothiri-1"), Nampoothiri et al. (US Patent Application Publication 2002/0155555; "Nampoothiri-2"), Nampoothiri et al. (US Patent Application Publication 2004/0092710; "Nampoothiri-3"), Nampoothiri et al. (US Patent 6,949,374; "Nampoothiri-4") Mockel et al. (US Patent Application Publication 2003/0087400; "Mockel-1"), Mockel et al. (US Patent 6,759,218; "Mockel-2"), Mockel et al. (US Patent Application Publication 2003/0166173; "Mockel-3), Dusch et al. (US Patent Application Publication 2005/0196848; "Dusch"), Wehmeier et al. (US Patent Application Publication 2003/0148476; "Wehmeier"), Dunican et al. (US Patent Application Publication 2003/0138917; "Dunican-1"), Dunican et al. (US Patent Application Publication 2004/0214219; "Dunican-2"), Dunican et al. (US Patent 6,797,509; "Dunican-3") Dunican et al. (US Patent Application Publication 2005/0112730; "Dunican-4"), Dunican et al. (US Patent 6,825,029; "Dunican-5") in view of Kramer (*J. Biotechnol.* 45:1-21, 1996; cited in the PTO-892 filed on 4/20/04), Grabau et al. (*J.*

Bacteriol. 160:1088-1092, 1984; cited in the 9/3/02 IDS), Chang et al. (*J Bacteriol* 154:756-762, 1983; cited in the PTO-892 filed on 10/19/05; "Chang-1"), and Chang et al. (*J. Bacteriol.* 167:312-318, 1986; cited in the IDS filed on 9/3/02; "Chang-2").

The applied references of Farwick-1, Farwick-2, Farwick-3, Farwick-4, Farwick-5, Burke-1, Burke-2, Burke-3, Burke-4, Burke-5, Hans, Nampoothiri-1, Nampoothiri-2, Nampoothiri-3, Nampoothiri-4, Mockel-1, Mockel-2, Mockel-3, Dusch, Wehmeier, Dunican-1, Dunican-2, Dunican-3, Dunican-4, and Dunican-5 appear to have a common inventor and/or assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

The examiner has made an earnest effort to exhaustively identify references that constitute prior art under 35 U.S.C. 102(e) having a common inventor and/or assignee with the instant application. However, since numerous references appear to constitute prior art under 35 U.S.C. 102(e) having a common inventor and/or assignee with the instant application, it is possible a reference or references was/were inadvertently overlooked. In the interest of compact prosecution, the examiner requests that applicant identify any other reference(s) that constitute(s) prior art under 35 U.S.C. 102(e) having a common inventor and/or assignee with the instant application. Applicant's cooperation will allow the examiner to focus on more substantive issues in the examination of the instant application.

The applied references of Farwick-1, Farwick-2, Farwick-3, Farwick-4, Farwick-5, Burke-1, Burke-2, Burke-3, Burke-4, Burke-5, Hans, Nampoothiri-1, Nampoothiri-2, Nampoothiri-3, Nampoothiri-4, Mockel-1, Mockel-2, Mockel-3, Dusch, Wehmeier, Dunican-1, Dunican-2, Dunican-3, Dunican-4, OR Dunican-5 each teaches L-amino acid production using a *C. glutamicum* bacterium with an attenuated *poxB* gene. None of these references teaches L-amino acid production using an *E. coli* with an attenuated *poxB* gene.

The reference of Kramer teaches that *C. glutamicum* and *E. coli* are the workhorses of industrial amino acid production. See particularly p. 1.

The reference of Grabau teaches cloning of an *E. coli* *poxB* gene (abstract).

Chang-1 teaches an *E. coli* with an inactivated *poxB* gene by insertional mutagenesis and Chang-2 teaches an *E. coli* expressing a PoxB polypeptide with a C-terminal deletion that substantially decreases PoxB activity.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of Farwick-1, Farwick-2, Farwick-3, Farwick-4, Farwick-5, Burke-1, Burke-2, Burke-3, Burke-4, Burke-5, Hans, Nampoothiri-1, Nampoothiri-2, Nampoothiri-3, Nampoothiri-4, Mockel-1, Mockel-2, Mockel-3, Dusch, Wehmeier, Dunican-1, Dunican-2, Dunican-3, Dunican-4, OR Dunican-5 AND Kramer, Grabau, Chang1, and Chang2 to modify an *E. coli* host cell by inactivating a chromosomal *poxB* gene, culture the resulting *E. coli*, isolate the resulting medium and cell extract, determine the levels of resulting L-amino acids, and isolate the L-amino acid from the medium or cells. One would have been motivated to do this because the reference of Farwick-1, Farwick-2, Farwick-3, Farwick-4, Farwick-5, Burke-1, Burke-2, Burke-3, Burke-4, Burke-5, Hans, Nampoothiri-1, Nampoothiri-2, Nampoothiri-3, Nampoothiri-4, Mockel-1, Mockel-2, Mockel-3, Dusch, Wehmeier, Dunican-1, Dunican-2, Dunican-3, Dunican-4, OR Dunican-5 teaches L-amino acid production using a *C. glutamicum* having such a modification, and like *C. glutamicum*, *E. coli* is used to produce L-amino acids as noted by Kramer. One would have had a reasonable expectation of success to modify an *E. coli* host cell by inactivating a chromosomal *poxB* gene, culture the resulting *E. coli*, isolate the resulting medium and cell extract, determine the levels of resulting L-amino acids, and isolate the L-amino acid from the medium or cells because of the results of Farwick-1, Farwick-2, Farwick-3, Farwick-4,

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Farwick-5, Burke-1, Burke-2, Burke-3, Burke-4, Burke-5, Hans, Nampoothiri-1, Nampoothiri-2, Nampoothiri-3, Nampoothiri-4, Mockel-1, Mockel-2, Mockel-3, Dusch, Wehmeier, Dunican-1, Dunican-2, Dunican-3, Dunican-4, OR Dunican-5 AND Kramer, Grabau, Chang-1, and Chang-2. Therefore, claims 23, 25-28, 33, and 39-42, drawn to the method described above, would have been obvious to one of ordinary skill in the art.

Claim Rejections - Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

[7] Claims 23, 25-28, 33, and 39-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over: 1) claim 44 of co-pending US non-provisional application 10/794,417 (the '417 application); claim 7 of co-pending US non-provisional application 10/483,413 (the '413 application); claim 22 of co-pending US non-provisional application 10/812,315 (the '315 application); and claim 33 of co-pending US non-provisional application 11/350,043 (the '043 application).

[8] Claims 23, 25-28, 33, and 39-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 28 of US Patent 7,319,026 (the '026 patent).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the '417, '413, '315, and '043 applications and the '026 patent anticipate claims 23, 25-28, 33, and 39-42 herein or the specifications of the applications or patent support an embodiment that would anticipate claims 23, 25-28, 33, and 39-42. Claims 23, 25-28, 33, and 39-42 of the instant application cannot be considered to be patentably distinct over the claims of the '417, '413, '315, and '043 applications and the '026 patent as noted above when there is a specifically recited embodiment that falls within the scope of claims 23, 25-28, 33, and 39-42 herein. Alternatively, claims 23, 25-28, 33, and 39-42 cannot be considered to be patentably distinct when there is a specifically disclosed embodiment in the applications that supports the claims and falls within the scope of claims 23, 25-28, 33, and 39-42 herein because it would have been obvious to one of ordinary skill in the art to modify the claimed methods by specifically using an *E. coli* host with an inactivated *poxB* gene.

One of ordinary skill in the art would have been motivated to do this because that embodiment is disclosed as being a preferred embodiment within the claims.

The examiner has made an earnest attempt to identify those patents and/or co-pending applications for purposes of rejecting or provisionally rejecting the claims for double patenting. However, it is noted that numerous co-pending applications have been filed and/or continue to be filed, and/or patents have issued disclosing subject matter that is related to the instant application. In the interest of compact prosecution, the examiner requests that: 1) applicants identify any patent(s) and/or co-pending application(s) that claim(s) subject matter that may necessitate a double patenting rejection, an obviousness-type double patenting rejection, a provisional double patenting rejection, or a provisional obviousness-type double patenting rejection; 2) identify the claims of the patents and/or co-pending applications that claim identical or similar subject matter; 3) identify the corresponding claims of the instant application, and 4) take the appropriate action, e.g., cancel claims to preempt a statutory double patenting rejection and/or file a terminal disclaimer to preempt an obvious-type double patenting rejection or provisional rejection. Applicants' cooperation in following steps 1) to 4) above is appreciated as this will allow the examiner to focus on more substantive issues in the examination of the instant application.

RESPONSE TO ARGUMENT: Applicant requests the provisional rejections based on claims of the '417, '413, and '315 applications be held in abeyance with respect to the remaining applications. This is not found persuasive to overcome the

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provisional rejections, which are maintained at least for reasons of record and reasons set forth above.

Requirements for Deposit of Biological Material

[9] It is noted that claims 35-38 are drawn to microorganisms. It appears applicant has complied with the requirements for deposit of biological material in view of the remarks filed on 7/20/04 at p. 8, top.

Conclusion

[10] Status of the claims:

Claims 23, 25-28, 33, and 35-42 are pending.

Claims 23, 25-28, 33, and 39-42 are rejected.

Claims 35-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Monday to Friday, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David J. Steadman/
David J. Steadman, Ph.D.
Primary Examiner
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